REMARKS/ARGUMENTS

Claims 15-17 are active.

Claim 15 is amended to incorporate Claim 23. Claim 23 is cancelled.

No new matter is added.

The Examiner has maintained the rejections based on the publication of Katakam et al with Wu. The separate rejection of Claim 24 further in view of Toschi is no longer applicable as Claim 24 has been cancelled.

In the rejection, the differences between FSH and HGH are acknowledged but nonetheless still believes that sufficient motivation exists to apply the methodology of Katakam to FSH. Applicants continue to disagree. Notably, the rejection states "it would have been obvious to one of ordinary skill in the art to apply the same method on other proteins." The rejection has failed to address or even acknowledge that while it may be obvious to try, there must be a reasonable expectation of success and the dramatic differences in the two proteins at issue here cannot be reasonably expected to behave in similar manners. Anyone who has ever performed protein purifications would know this as true.

As to Applicants previous argument that one would not have used poloxamer 188 because of its poor performance in Katakam, the Examiner points to the use of this poloxamer "above cmc." The Examiner also points out that the concentrations that are in the claims are above the cmc concentration where Katakam shows equivalent performance. See the Official Action at page 4.

As apparent from the claims presented in this paper, the concentration of Poloxamer 188 in the claimed method is 100 μg/ml.

According to Katakam et al. (see Table 1, page 147) the **cmc** of Poloxamer 188 is 0.0055 g/dl, which is equal to 0.0055 g/100 ml.

The concentration of a solution is often expressed as a "weight/volume percentage"; the percentage is calculated from the weight of solute in grams (g), divided by the volume of solvent in milliliters (ml): [Mass(g) / Volume(ml)] × 100 = %. In this case: (0.0055 g/100 ml) × 100 = **0.0055%**, which is the cmc of Poloxamer 188 according to Katakam et al.

Based on this and looking at the results reported on Table 1, it possible to conclude that Poloxamer 188, amongst those tested, is the worst stabilizer at a concentration between 0.001% (below cmc) and 0.0055% (at cmc). According to Table 1, Poloxamer 188 becomes a good stabilizer at a concentration of 0.2%, which is over 36 times of the cmc of Poloxamer 188 according to Katakam et al.

To compare the concentrations of Poloxamer 188 tested in Katakam et al. with that recited in Claim 15 (100 μg/ml) Applicants calculate those concentrations to the same units as follows:

100 μg/ml = 10000 μg/100 ml = 0.01 g/100 ml which, applying the formula above, corresponds to **0.01%**, i.e. a little less than double the cmc of Poloxamer 188 according to Katakam et al. (0.01/0.0055=1.81).

Therefore, it follows that the concentration of Poloxamer 188 recited in Claim 15 (0.01%) is much closer to the "non-working" concentration of Poloxamer 188 (0.0055%), according to Katakam et al., than to the "working" one (0.2%).

In view of the above, it results that the skilled person had no motivation to try Poloxamer 188 as stabilizer at a concentration which is less than double the cmc, knowing in addition that Poloxamer 188 works well at much higher concentrations, i.e. concentrations over 36 times the cmc.

In conclusion, the fact that Poloxamer 188 is a good stabilizer for FSH at a concentration, which is very close to that which showed very negative results for hGH, is an evidence that these two proteins have totally different properties. Therefore, one would not

have not been motivated to apply the teaching of Katakam, focused on hGH, to FSH as in the present claims.

Reconsideration and withdrawal of the rejection is requested.

A Notice of Allowance is also requested.

Respectfully submitted,

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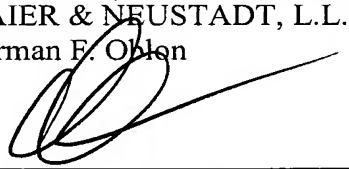
Norman F. Oblon



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